

REMARKS

The claims have been amended to place the application in better condition for allowance or appeal. In particular, claims 44 and 45 have been canceled.

35 U.S.C. § 112, First Paragraph, Rejection of Claims 21, 27, 28 and 43-45 (Enablement)

The Examiner has maintained the rejection of claims 21, 27, 28 and 43-45 under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims, essentially for the reasons of record presented in the previous Office Action, mailed June 17, 2003.

In addition, however, in the instant Office Action the Examiner dismisses the Furness Declaration, stating that “the declaration does not establish enablement of mutant and variant molecules that may differ in structure and function from wild-type sequences. Notwithstanding, SEQ ID NO:3 and 3 have not been clearly characterized....”.

Applicants Response

Applicants have canceled claims 44 and 45 reciting variants of the polypeptides of SEQ ID NOs:3 and 5 in purely structural terms. The remaining claims recite variants and fragments of SEQ ID NOs:3 and 5 as “having apoptotic activity”. The Examiner has previously withdrawn the utility rejection under 35 U.S.C. § 101, and the enablement rejection based on an alleged lack of utility for SEQ ID NOs:3 and 5 in the Office Action mailed September 7, 2001. Clearly, therefore, the Examiner does not deny the utility and enablement of these polypeptides based on their identification as “apoptotic proteins” as asserted in the specification. Therefore with the previous amendment of claim 21 to recite only “variants” and “biologically active” fragments having apoptotic activity, and the cancellation of those remaining claims not reciting the activity of SEQ ID NOs:3 and 5, applicants submit that claims 21, 27, 28 and 43 are fully enabled with respect to SEQ ID NOs:3 and 5, biologically active fragments of SEQ ID NOs:3 and 5, and naturally occurring variants of SEQ ID NOs:3 and 5 having at least 90% sequence identity to SEQ ID NOs:3 and 5, all of which are recited as having apoptotic activity according to the assay described at page 58, lines 16-30 of the specification. Immunogenic fragments of SEQ ID NOs:3 and 5 are fully enabled for the reasons previously given in the Response of Office Action filed September 17, 2003, at page 12.

For all of the above reasons, applicants submit that claims 21, 27, 28 and 43 are fully enabled by the specification and the common knowledge of one skilled in the relevant art at the time the application was filed, and request withdrawal of the rejection of these claims under 35 U.S.C. § 112, first paragraph, for lack of enablement.

35 U.S.C. § 112, First Paragraph, Rejection of Claims 21, 22, 27, 28 and 43-45

The Examiner has maintained the rejection of claims 21, 22, 27, 28 and 43-45 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, essentially for the reasons of record.

The Examiner stated specifically that “The written description guidelines mandate that a representative number of species belonging to a genus demonstrate function and structure commensurate in scope be disclosed and be in possession of Applicant. It is essential that there is a functional and structural correlation which defines the species. The claims and specification provide insufficient evidence setting forth the critical features of the claimed invention and its relation to its critical function” (Office Action, page 5).

Applicants Response

The amendment canceling claims 44 and 45 have been discussed. Claim 21 and dependent claims 22, 27, 28 and 43 now recite only naturally occurring variants of SEQ ID NOs:3 and 5 having at least 90% sequence identity with SEQ ID NOs:3 and 5, and biologically active fragments of SEQ ID NOs:3 and 5 “having apoptotic activity”. Applicants disagree that the written description guidelines “mandate that a representative number of species belonging to a genus demonstrate function and structure commensurate in scope be disclosed and be in possession of Applicant” in order to provide an adequate written description of the genus. Applicants refer to examples provided in the training materials for the application of the guidelines entitled “Synopsis of Application of Written Description Guidelines”, in particular, to Example 14:Product by Function (page 46). In this example, the claim in question recites:

A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical with SEQ ID NO:3 and which catalyze the reaction of A-B”

The example describes the specification as providing the sequence of SEQ ID NO:3 and an assay for measuring the reaction of A~B. The example considers the single species of SEQ ID NO:3 disclosed as representative of the genus because:

... all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by members of the genus.

Applicants therefore submit that for the same reasons, variants of SEQ ID NOs:3 or 5, as described in claim 21, having at least 90% sequence identity with SEQ ID NOs:3 or 5 and which possess apoptotic activity according to the assay described in the specification are likewise adequately described, and the skilled artisan would conclude that applicant was in possession of said variants.

Withdrawal of the rejection of claims 21, 22, 27, 28 and 43 under 35 U.S.C. § 112, first paragraph is therefore requested.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited. Applicants further request that upon allowance of claim 21, claims 24, 25, 29, 30, 41 and 42 be rejoined and examined as process claims that depend from and are of the same scope as product claim 21 in accordance with *In re Ochiai* and the MPEP § 821.04.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

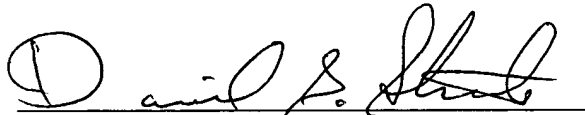
Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,

INCYTE CORPORATION

Date:

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